APR 17 2014

510(k) Summary

Date:	14 February 2014
Sponsor:	Paragon 28, Inc. 4B Inverness Ct. E., STE 280 Englewood, Colorado 80112 Phone: (888) 728-1888 Facsimile: (888) 728-1220
Contact Person:	Frank S. Bono, Chief Technology Officer
Trade Names:	ParaLock Plating System™
Device Classification	Class II
Regulations, Product Codes, Classification & Common Names:	888.3030, HRS, Single/multiple component metallic bone fixation appliances and accessories, bone plate system 888.3040, HWC, Smooth or threaded metallic bone fixation fastener, bone screw 888.3030, HTN, Single/multiple component metallic bone fixation appliances and accessories, washer
Device Description:	The ParaLock Plating System™ and TUFFNEK™ screws are lower extremity fixation systems. ParaLock Plates are offered in "mini" and "standard" set sizes in a variety of shapes based upon the anatomical fixation required. TUFFNEK™ screws are also offered in "mini" and "standard" sets and, in addition, in locking and non-locking versions. Size-matched washers are available for use with the TUFFNEK™ screws when the latter are used for fixation without the plates.
Intended Use:	The ParaLock Bone Plates and TUFFNEK™ Bone Screws of the ParaLock Plating System™ are indicated for use in stabilization and fixation of fractures or osteotomies; intra and extra articular fractures, joint depression, and multi-fragmentary fractures; revision procedures, joint fusion and reconstruction of small bones of the toes, feet and ankles including the distal tibia, talus, and calcaneus. The system can be used in both adult and pediatric patients. In addition, the TUFFNEK™ non-locking, titanium alloy (Ti6Al4V ELI) screws and washers are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair and fracture fixation, appropriate for the size of the device.
Materials:	The ParaLock and TUFFNEK™ implants are manufactured from medical grade titanium (per ASTM F67) and titanium alloy (per ASTM F136).
Predicate Devices:	• The Normed Extremity Titanium Hand and Small Fragment System, the Normed Titanium Calcaneus Plating with Locking Screw System and the Normed Titanium Osteotomy Plating System (Osteomedics Inc – K011118, K022324 and K022325, respectively) • The Wright Medical ORTHOLOC™ 3Di Hallux System, The Wright Medical ORTHOLOC™ 3Di Ankle Fusion Plating System and The Wright Medical ORTHOLOC™ 3Di Midfoot/Flatfoot System (Wright Medical Technology, Inc. – K120359, K121425 and K121651, respectively) • CHARLOTTE™ Snap-Off Screw (Wright Medical Technology, Inc. K043583, K050819) • M3-X Extremity Fixation (OsteoMed Corp., K924018) • The Arthrex Titanium Opening Wedge Osteotomy System, the Arthrex Small Fragment Plates and Screws, Low Profile Plate and Screw System, the Arthrex Low Profile Screws and The Arthrex Distal Extremity Plate System (Arthrex, Inc. – K032187, K040907, K052614, K103705 and K111253, respectively)

- The Stryker® Foot Plating System (Howmedica Osteonics – K063875)
- The Mini MaxLock Extreme® Plating System (OrthoHelix Surgical Designs Inc. - K101962, K120157 & K121437)
- OsteoMed Foot Plating System ("FPS" OsteoMed LP – K091614)

Performance Data: Mechanical testing of the worst case ParaLock Plates included static and dynamic bending performed according to ASTM F382. Mechanical testing of the worst case TUFFNEK™ screws included torsion, insertion/removal and pullout performed according to ASTM F543. The mechanical test results and theoretical comparisons demonstrated that the mechanical performance of the ParaLock Plating System™ and TUFFNEK™ screws is substantially equivalent to the predicate devices.

Technological Characteristics: The ParaLock Plating System™ and TUFFNEK™ screws possess the same technological characteristics as one or more of the predicate devices. These include:

- performance (as described above),
- basic design (screws and plates in various shapes),
- material (titanium and/or titanium alloys) and
- sizes (dimensions are comparable to those offered by the predicate systems).

Therefore the fundamental scientific technology of the ParaLock Plating System™ is the same as previously cleared devices.

Conclusion: The ParaLock Plating System™ and TUFFNEK™ screws possess the same intended use and technological characteristics as the predicate devices. Therefore the ParaLock Plating System™ and TUFFNEK™ screws are substantially equivalent for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 17, 2014

Paragon 28, Inc.
% Ms. Karen E. Warden, Ph.D.
Representative/Consultant
BackRoads Consulting, Inc.
PO Box 566
Chesterland, Ohio 44026-0566

Re: K140397
Trade/Device Name: ParaLock Plating System™
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories.
Regulatory Class: Class II
Product Code: HRS, HWC, HTN
Dated: March 3, 2014
Received: March 4, 2014

Dear Dr. Warden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K140397

Device Name: ParaLock Plating System™

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Prescription Use __X__ OR Over-the-Counter Use_____

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices